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| 10/808,897 | 03/25/2004 | Winthrop D. Childers | 200314128 | 8950 |

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| EXAMINER | |
|---|---|
| NOGUEROLA, ALEXANDER STEPHAN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1753 | |

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/808,897 | CHILDERS ET AL. | |
| | Examiner | Art Unit | |
| | ALEX NOGUEROLA | 1753 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-21,23 and 24* is/are rejected.

7)☒ Claim(s) *9 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS s of 8/20/2004, 3/25/2004*.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker et al. (US 5,993,632) ('Becker").

Addressing claim 1, Becker discloses a transporter of a biodevice for transporting cells during a transport time period (abstract), the transporter comprising

a motion-inducing apparatus (col. 16:51-55) configured to induce transportation of the cells along a transport path of the device between other operative portions of the biodevice (abstract and Figures 2A and 2B), the apparatus comprising an electrode arrangement configured to apply a non-uniform electric field to the cells (abstract; Figures 1A and 1B; col. 3:52 – col. 4:4; and col. 4:45-67); and

a transport control unit coupled to the motion-inducing apparatus to control transportation of the cells and providing control signals to the motion-inducing apparatus during the transport time period (such a unit is implied since both fluid flow speed and

the dielectrophoresis fields can be controlled. See col. 11:18-24; col. 18:32-33 ("This fluid can be controlled to flow at different speeds.") and col. 18:57-61) to:

induce a primary motion of the cells to drive transportation of the cells along the transport path (Figures 1B, 1C, 2A, and 2B (fluid flow arrow); col. 11:18-24; col. 18:32-33 ("This fluid can be controlled to flow at different speeds.") ; and col. 16:51-55, which discloses a digital syringe pump and a peristaltic pump); and

induce a secondary motion of the cells to discourage aggregation of the cells during transportation of the cells (Figure 2A; col. 6:32-67).

Addressing claim 2, for the additional limitation of this claim see the abstract, fourth sentence; and Figures 2A and 2B.

Addressing claim 3, for the additional limitation of this claim see Figures 1B, 1C, which discloses electrodes; and col. 16:51-55, which discloses a digital syringe pump and a peristaltic pump

Addressing claim 4, for the additional limitation of this claim see Figures 2A and 2B and note that the pump outlet (15) is disposed vertically between the electrode grids (5).

Addressing claim 5, for the additional limitation of this claim see the embodiment of Figure 2B. The second apparatus comprises chamber 10, which has substrate 5, upon which are the electrode grids for inducing secondary motion of the cells. Only a small portion of the first apparatus (pump) is shown – its outlet. As seen in Figure 2B the transport path is substantially parallel to the outlet of the first apparatus and the second apparatus.

Addressing claim 6, for the additional limitation of this claim see col. 16:51-55, which discloses a digital syringe pump and a peristaltic pump .

Addressing claims 7 and 20, for the additional limitations of these claims see col. 9:47-57 and col. 10:9-24.

Addressing claim 8, for the additional limitations of this claim see 1B, 1C, 2A and 2B and col. 6:6:40-48 and col. 12:26-52. Note that different types of non-uniform electric fields are disclosed, not just traveling wave (twDEP).

Addressing claim 19, Becker discloses an apparatus for moving cells on an electronic biodevice during a transport time period (abstract), the apparatus comprising:

means for imparting a primary motion of the cells on the biodevice to transport the cells between stations on the biodevice (Figures 1B, 1C, 2A, and 2B (fluid flow

arrow); col. 11:18-24; col. 18:32-33 ("This fluid can be controlled to flow at different speeds."); and col. 16:51-55, which discloses a digital syringe pump and a peristaltic pump), and a secondary motion of the cells to prevent aggregation of the cells during the cell transport (Figures 1B, 1C, 2B; col. 6:32-67); and

means for controlling the means for imparting, via control signals, to selectively activate the primary motion and the secondary motion to maintain substantially aggregation-free transport of the cells during the transport time period (such a means is implied since both fluid flow speed and the dielectrophoresis fields can be controlled. See col. 11:18-24; col. 18:32-33 ("This fluid can be controlled to flow at different speeds.") and col. 18:57-61.

3. Claims 1-4, 6, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Crane et al. (US 5,489,506) ("Crane").

Addressing claim 1, Crane discloses a transporter of a biodevice for transporting cells during a transport time period (abstract), the transporter comprising

a motion-inducing apparatus (abstract – last sentence) configured to induce transportation of the cells along a transport path of the device between other operative portions of the biodevice (abstract and Figure 1), the apparatus comprising an electrode arrangement configured to apply a non-uniform electric field to the cells (abstract; Figure 3; and col. 3:12-20); and

a transport control unit coupled to the motion-inducing apparatus to control transportation of the cells and providing control signals to the motion-inducing apparatus during the transport time period (such a unit is implied since both fluid flow speed and the dielectrophoresis fields can be controlled. See col. 3:12-20 and col. 3:54-57) to:

induce a primary motion of the cells to drive transportation of the cells along the transport path (abstract-last sentence); and

induce a secondary motion of the cells to discourage aggregation of the cells during transportation of the cells (abstract-fourth sentence and col. 3:12-20).

Addressing claim 2, for the additional limitation of this claim see Figure1 and col. 3:12-45.

Addressing claim 3, for the additional limitation of this claim see Figure 3 and abstract-fourth sentence.

Addressing claim 4, for the additional limitation of this claim see Figures 1-3 and col. 4:65-67.

Addressing claim 6, for the additional limitation of this claim see abstract, last sentence.

Addressing claim 19, Crane discloses an apparatus for moving cells on an electronic biodevice during a transport time period (abstract), the apparatus comprising:

means for imparting a primary motion of the cells on the biodevice to transport the cells between stations on the biodevice (abstract-last sentence), and a secondary motion of the cells to prevent aggregation of the cells during the cell transport (abstract-fourth sentence and col. 3:12-20); and

means for controlling the means for imparting, via control signals, to selectively activate the primary motion and the secondary motion to maintain substantially aggregation-free transport of the cells during the transport time period (such a means is implied since both fluid flow speed and the dielectrophoresis fields can be controlled. See col. 3:12-20 and col. 3:54-57).

4. Claims 1-4 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lock et al. (WO 01/05514 A1) ('Lock").

Addressing claim 1, Lock discloses a transporter of a biodevice for transporting cells during a transport time period (abstract and page 3:28-34 and page 14:16-31), the transporter comprising

a motion-inducing apparatus (Figure 9) configured to induce transportation of the cells along a transport path of the device between other operative portions of the biodevice (page 14:8 – page 15:4), the apparatus comprising an electrode arrangement

configured to apply a non-uniform electric field to the cells (page 15:6-13; Also see page 16:3-22); and

a transport control unit coupled to the motion-inducing apparatus to control transportation of the cells and providing control signals to the motion-inducing apparatus during the transport time period (signal generator 26 – page 15:19-29) to:

induce a primary motion of the cells to drive transportation of the cells along the transport path (page 14:8-14; page 14:25 – page 15:4; and claims 4 and 21); and

induce a secondary motion of the cells to discourage aggregation of the cells during transportation of the cells (page 14:19-25 and claim 3).

Addressing claim 2, for the additional limitation of this claim see page 14:33 – page 15:4 and page 16:13-22.

Addressing claim 3, for the additional limitation of this claim see page 16:24-34, which discloses using two TWD arrays.

Addressing claim 4, for the additional limitation of this claim see page 16:24-25.

Addressing claim 19, Lock discloses an apparatus for moving cells on an electronic biodevice during a transport time period (abstract), the apparatus comprising:

means for imparting a primary motion of the cells on the biodevice to transport the cells between stations on the biodevice (page 14:8-14; page 14:25 – page 15:4; and claims 4 and 21), and a secondary motion of the cells to prevent aggregation of the cells during the cell transport (page 14:19-25 and claim 3); and

means for controlling the means for imparting, via control signals, to selectively activate the primary motion and the secondary motion to maintain substantially aggregation-free transport of the cells during the transport time period (signal generator 26 – page 15:19-29).

Addressing claims 20, for the additional limitation of this claim see page 14:8 – page 15:4.

Addressing claim 21, for the additional limitations of this claim see Claim 3 and page 9:25 –page 10:36, which discloses levitating a particle.

***Claim Rejections - 35 USC § 103***

5. Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becker et al. (US 5,993,632) ('Becker").

Addressing claim 1, Becker discloses a transporter of a biodevice for transporting cells during a transport time period (abstract), the transporter comprising

a motion-inducing apparatus (col. 16:51-55) configured to induce transportation of the cells along a transport path of the device between other operative portions of the biodevice (abstract and Figures 2A and 2B), the apparatus comprising an electrode arrangement configured to apply a non-uniform electric field to the cells (abstract; Figures 1A and 1B; col. 3:52 – col. 4:4; and col. 4:45-67); and

a transport control unit coupled to the motion-inducing apparatus to control transportation of the cells and providing control signals to the motion-inducing apparatus during the transport time period (such a unit is implied since both fluid flow speed and the dielectrophoresis fields can be controlled. See col. 11:18-24; col. 18:32-33 ("This fluid can be controlled to flow at different speeds.") and col. 18:57-61) to:

induce a primary motion of the cells to drive transportation of the cells along the transport path (Figures 1B, 1C, 2A, and 2B (fluid flow arrow); col. 11:18-24; col. 18:32-33 ("This fluid can be controlled to flow at different speeds.") ; and col. 16:51-55, which discloses a digital syringe pump and a peristaltic pump); and

induce a secondary motion of the cells to discourage aggregation of the cells during transportation of the cells (Figure 2A; col. 6:32-67).

Although Becker only *shows* electrode elements disposed on a first side of the transport path aligned above electrode elements disposed on the second side of the transport path (Figure 2B), Becker discloses a variety of electrode configurations including providing a plurality of electrode elements, such as interdigitated array or parallel array along both the first side and second side of the transport path, which would include electrode elements longitudinally spaced on different sides of the transport path. See col. 3:54 – col. 4:44 and col. 9:47-62. Becker further discloses several modes of operating the electrode elements, including traveling wave. See col. 6:49-67. Barring a showing to the contrary, such as unexpected result, the claimed electrode configurations and modes of operation are just optimizing the electrode configuration and electrical fields for the desired separation of cells. See also col. 23:64 – col. 24:14. For claims 14 and 16 note that electrorotation is also disclosed. See col. 22:17-24.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 requires the primary motion to be produced by the first portion of the electrode array and to comprises at least one of the traveling wave dielectrophoretic field and a fluid flow pressure drop. Does this mean that the electrode array can produce a fluid pressure drop or does it mean that the electrode field can produce an electrical field, such as a traveling wave dielectrophoretic field, to produce primary motion and that a fluid pressure drop can also contribute to this primary motion?

8. Note that dependent claims will have the deficiencies of base and intervening claims.

***Specification***

9. The disclosure is objected to because of the following informalities: on page 1 the serial numbers of two U.S. Patent Applications are missing.

10. Appropriate correction is required.

***Allowable Subject Matter***

11. Claims 9 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claims 23 and 24 would be allowable if rewritten to overcome the rejection under

35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

a) Claims 9 and 22: (i) in claim 9 the combination of limitations requires the first apparatus to be overlaid onto the second apparatus in a single substrate, with both the first apparatus and the second apparatus disposed underneath the transport path, and wherein the second apparatus comprises a piezoelectric device configured to apply a vibratory force to the cells for preventing aggregation of the cells during the transport period; and (ii) in claim 22 the combination of limitations requires the means fro imparting the secondary motion of the cells to comprise a piezoelectric device disposed below the first portion of the electrode array, wherein the piezoelectric device is configured to apply an ultrasonic force on the cells.

In Becker the first apparatus or means for imparting a primary motion of the cells is a pump not overlaying or above the second apparatus, which is a dielectrophoresis device configured to apply a dielectrophoresis force for preventing aggregation of the cells during the transport period. See the abstract; Figures 1b, 1C, 2A, and 2B; and col. 16:51-55, which discloses a digital syringe pump and a peristaltic pump.

In Crane the first apparatus or means for imparting a primary motion of the cells is a pump not overlaying or above the second apparatus, which is a RF (dielectrophoresis) device configured to apply an electrical force (dielectrophoresis) force for preventing aggregation of the cells during the transport period. See the abstract and Figures 1-3.

In Lock the first apparatus means for imparting a primary motion of the cells may be a dielectrophoresis device (first electrode grid) for generating a traveling-wave electrode field and the second apparatus may be a second dielectrophoresis device (second electrode grid) for "static" dielectrophoresis. No piezoelectric device is mentioned. Also these two devices are not mentioned as overlying each other, but as being on opposing spaced substrates or at an angle to each other. See page 15, line 6 - page 16, line 26.

Wang et al. (US 6,881,314 B1) discloses a transporter of a device which may be use for transporting cells during a transport time period. See Figure 7 and col. 2:49 – col. 3:21. Although Wang et al. also discloses having a first apparatus for affecting cell motion or means for imparting a primary motion of the cells overlaying a second apparatus for affecting the cell motion, the second apparatus comprising a piezoelectric device configured to apply a vibratory force to the cells, the first apparatus does not induce a primary motion of the cells to drive transport of the cells along the transport path. The first apparatus works in conjunction with the second apparatus to induce a secondary motion normal to the primary motion of the cells for more refined separation in the secondary

motion dimension. Primary motion is induced by means, such as a pump upstream from these apparatuses. See Figure 7; col. 31:45 – col. 32:16; col. 29:59 – col. 30:1; col. 30:58-60; and col. 29:45-52.

b) Claim 23: the combination of limitations requires the transport control unit to apply the primary motion and the secondary motion in alternating cycles. In Becker and Lock the primary motion and secondary motion are applied simultaneously. See the abstract and Figures 2A and 2B in Becker. See page 15, lines 2-4 and pager 16, lines 16-22 in Lock.

c) Claim 24 depends from allowable claim 23.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
April 3, 2006